Remarks

The Office Action mailed September 4, 2002 has been received and reviewed. Claims 1, 6, 11, 20-29 and 31-35 having been amended, claims 5, 10, 12, and 36 having been canceled and claims 37-39 having been added, the pending claims are claims 1-4, 6-9, 11, 13-35 and 37-39. Reconsideration and withdrawal of the rejections are respectfully requested.

The claims have been amended to clarify the claimed invention. Claim amendments have not been made to narrow the claimed invention. Support for claims amendments is found throughout the specification. For example, support for the amendment "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1" in claims 1, 6, 11, 20, 27, 29 and 34 is found on p. 11, line 24 and p. 12, lines 11-13 of the specification. Support for the amendment "leukocyte" in claims 20-29 and 31-35 is found on p.2, line 17 of the specification. Support for new claim 37 is found in original claim 1; support for new claim 38 is found in original claim 6; and support for new claim 39 is found in original claim 11.

Traverse of Restriction Requirement

In response to the Restriction Requirement mailed June 17, 2002, Applicants elected, with traverse, Group 1 (claims 1-35), drawn to methods of contacting cells with SEQ ID NO:1 (Response to Restriction Requirement, filed July 17, 2002). Applicants continue to traverse this Restriction Requirement. Applicants submit that the restriction requirement, limiting Applicant to only one of SEQ ID NO:1-35, places an undue burden on the Applicants by requiring payment of 34 separate filing fees for examination of the nonelected claims, as well as the added costs associated with prosecuting 35 applications and maintaining 35 patents.

Further, Applicants direct the Examiner's attention to the fact that claims 20 and 29 are linking claims with respect to the use of the sequences in a method for modulating leukocyte proliferation. Accordingly, the Examiner's restriction appears to be more

appropriately an election of species with respect to specific sequences. See MPEP 809.02. Thus, Applicants traverse on the grounds that the generic (linking) claims 20 and 29 includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner. Applicants also request rejoinder and that the requirement be withdrawn upon the finding of an allowable genus.

Examiner Interview

An Examiner's Interview was held on October 15, 2002 between the Applicant's Representative and Examiners Nichols and Kemmerer. The claim rejections of record were discussed. Examiner Nichols and Kemmerer are thanked for the courtesy of this interview.

Information Disclosure Statements

Copies of PTO-1449s mailed June 11, 2001, and July 23, 2001, were considered by the Examiner on August 19, 2002, and included with the office action. It is noted that only some of the citations listed on the PTO-1449 mailed June 11, 2001, were considered and initialed by the Examiner. The Examiner is requested to provide an explanation of why citations on the PTO-1449 mailed on June 11, 2001 were not considered and initialed by the Examiner. As a courtesy, a copy of the PTO-1449 mailed June 11, 2001 is included as Exhibit A with this communication, for consideration by the Examiner.

Objections to the Specification

The Examiner objected to the specification for the following informalities; the misspelling of "downstream" on p.7, line19, and the recitation of a browser-executable hyperlink on p. 12, line 6. The specification has been amended to correct this spelling error and to remove the browser-executable hyperlink. Withdrawal of the objection to the specification is respectfully requested.

Objections to the Claims

The Examiner has objected to claims 1-35 for the recitation of non-elected inventions. Claims 1-4, 6-9, 11, 13-19, 27 and 34 have been amended to recite elected SEQ ID NO:1. Claims 20-26 and 29-33, as generic claims, need not be restricted to the elected SEQ ID NO:1. Withdrawal of this objection to the claims is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 1-35 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

Specifically, the Examiner stated that the specification does not enable one of skill in the art to practice the claimed invention with all "analogs." Claims 1-4, 6-9, 11, 13-19, 27, 28 and 34 are drawn to active analogs of SEQ ID NO:1, "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1." It is respectfully submitted that the specification provides ample guidance to allow one of skill in the art to make and use active analogs having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1. See, for example, p. 11, line 21 through p. 12, line 15 of the specification.

Further, the Examiner stated that the specification does not enable one of skill in the art to practice the claimed invention to modulate "the enormous range of blood cells." Claims 20-35 are drawn to leukocytes. Leukocytes, the white blood cell component of blood, are much less numerous than red blood cell component of blood, (the ratio between the two is around 1:700). It is respectfully submitted that the specification provides ample guidance to practice the claimed methods of modulating leukocyte proliferation. See, for example, Table 1, pages 19-20 of the specification, demonstrating the proliferation of human leukocyte cultures.

Withdrawal of this rejection of the claims under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §102 Rejection over Inglot et al.

The Examiner rejected claims 1-10 under 35 U.S.C. §102 as being anticipated by Inglot et al. (1996) Archivum Immunologiae et Therapiae Experimentalis 44:215-224. This rejection is respectfully traversed. It is respectfully submitted that Inglot et al. does not disclose methods of inducing a cytokine in a cell (claims 1-4) or modulating an immune response in a cell (claims 6-9) comprising contacting the cell with a peptide comprising SEQ ID NO:1, an active analog thereof, and combinations thereof, wherein an "active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1." Thus, the disclosure of Inglot et al. does not set forth each and every element of claims 1-10. According to MPEP § 2131 a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Withdrawal of this rejection under 35 U.S.C. §102(a) is respectfully requested.

The 35 U.S.C. §102 Rejection over Janusz et al.

The Examiner rejected claims 11-35 under 35 U.S.C. §102 as being anticipated by Janusz et al. (WO 98/14473). This rejection is respectfully traversed.

It is respectfully submitted that Janusz et al. does not disclose a method of modulating an immune response (claims 11, 13-19) or a method of modulating leukocyte proliferation (claims 27, 28, 34 and 35) comprising the administration of SEQ ID NO:1, an active analog thereof, and combinations thereof, wherein an "active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1." Thus, the disclosure of Janusz et al. does not

set forth each and every element of the claimed invention and withdrawal of this rejection under 35 U.S.C. §102(a), as anticipated by Janusz et al., is respectfully requested.

Further, it is respectfully submitted that Janusz et al. does not disclose a method of modulating leukocyte proliferation (claims 20-35), where proliferation is an increase in cell number (see p. 8, lines 10-15 and p. 18, lines 1-32 of the specification). Rather, the teachings of Janusz et al. are limited to the administration of colostrinin to provide an "immunotrophic action" (p. 1, line 30); to improve "the development of the immune system" (p.3, lines 15-16); "to stimulate the growth, maturation and differentiation of immunologically active cells" (p. 8, lines 4-5); and to stimulate the production of cytokines (p. 8., lines 7-10). Janusz et al. does not disclose an increase in leukocyte cell numbers, thus Janusz et al. does not disclose modulation of the proliferation of leukocytes.

The Examiner uses the doctrine of inherency to support these rejections. However, Applicants' Representatives submit that historically the inherency doctrine has been used to reject claims to a product that is alleged to be new when there is a process in the prior art that clearly yields the claimed product. The Examiner is requested to note that all the currently pending claims are directed to methods.

Furthermore, for inherency to apply, the missing descriptive information must necessarily be present in one of the cited documents such that one of skill in the art would recognize such a disclosure. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill'" (In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999) quoting Continental Can Co. v. Monsanto Co., 20 USPQ2d 1746 (Fed. Cir. 1991)).

Because the claimed methods are drawn to methods of modulating leukocyte proliferation comprising the administration of a leukocyte regulator "under conditions effective to change the number of leukocytes" (claims 20-35), there can be no recognition by one of skill in the art that modulating leukocyte proliferation is necessarily present in the teachings of Janusz

et al. Inherency must be a necessary result, not merely a possible result. "'Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" (In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999) quoting In re Oelrich, 212 USPQ 323 (Fed. Cir. 1981)). Furthermore, methods of modulating leukocyte proliferation are inherent only if there is at least a reasonable likelihood that one of skill in the art could have discovered or recognized it without specific guidance. That is, the subject matter relied upon must be disclosed in a manner to place it in possession of the public. (See, e.g., Akzo N.V. v. United States Int'l Trade Comm'n, 1 USPQ2d 1241 (Fed. Cir. 1986)). Clearly, this is not the situation with the documents cited by the Examiner. The teachings of Janusz et al. are limited to immunotrophic events, such as inflammation, and include no recognition of leukocyte proliferation.

For the reasons discussed above, the disclosure of Janusz et al. does not set forth each and every element of the invention of claims 10-35. Withdrawal of this rejection under 35 U.S.C. §102(a) is respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-4, 6-9, 11, 13-35 and 37-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Stanton et al.

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PATENT TRADEMARK OFFICE

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CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 183606717 US Date of Deposit: December 4, 2002
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

By: _____
Name: Sara E. Olson

APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE
Serial No.: 09/641,801
Docket No.: 265.00230101

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

In the Specification

The paragraph beginning at page 6, line 32, has been amended as follows:

Many nonspecific and specific immune responses are associated with leukocyte proliferation and differentiation. The overall immunological significance of the present invention can be, but is not limited to, the following: IFN-γ is a potent immunomodulater that is important for the development of the cytotoxic lymphocyte response (CTL). This immune response is considered to be very important in protecting humans and animals from a variety of bacterial, viral, parasitic, and fungal diseases. The fact that TNF-α is also induced is important because TNF-α is a major activator of macrophages, among other immune cells, which are important in host defense against infections. In addition, TNF-α has been shown to have activity against cancer, directly through its lytic activity and indirectly through macrophages. IL-10 is another important immune mediator that controls both IFN-γ and TNF-α production and action. Its production represent a negative feedback control for IFN-γ and TNF-α production. Another one of its hallmark activities is the control of antibody production during the humoral immune responses, which is certainly important in many types of infections. In addition to IL-10's immune activities, it also has been shown to play a role in the neuroendocrine system by modulating certain stress responses and immune responses. IL-10 has been shown to induce the production of corticotropin from pitutitary cells. Corticotropin works downstream [downstreanm] in the hypothalmic adrenal axis to induce glucocortico steroids that are inherently immunomodulatory. Like IL-10, the IL-4 is important in the development of B cell responses, which are the mediators of the humoral immune response. Finally, the IL-12 is an important IFN-γ inducer. Taken together these findings suggest that colostrinin and its component peptides have the ability to modulate via cytokine induction a variety of host-defense

mechanisms mediated by macrophages and lymphocytes at the cellular and humoral immune level as well as the neuroendocrine system.

The paragraph beginning at page 11, line 29, has been amended as follows:

As stated above, active analogs of colostrinin and its constituent peptides include polypeptides having structural similarity. Structural similarity is generally determined by aligning the residues of the two amino acid sequences to optimize the number of identical amino acids along the lengths of their sequences; gaps in either or both sequences are permitted in making the alignment in order to optimize the number of identical amino acids, although the amino acids in each sequence must nonetheless remain in their proper order. Preferably, two amino acid sequences are compared using the Blastp program, version 2.0.9, of the BLAST 2 search algorithm, available on the worldwide web at ncbi.nlm.nih.gov/gorf/b12.html [at http://www.ncbi.nlm.nih.gov/gorf/bl2.html]. Preferably, the default values for all BLAST 2 search parameters are used, including matrix = BLOSUM62; open gap penalty = 11, extension gap penalty = 1, gap x_dropoff = 50, expect = 10, wordsize = 3, and filter on. In the comparison of two amino acid sequences using the BLAST search algorithm, structural similarity is referred to as "identity." Preferably, an active analog of colostrinin or its constituent peptides has a structural similarity to colostrinin or one or more of its constituent peptides (preferably, one of SEQ ID NOs:1-30) of at least about 70% identity, more preferably, at least about 80% identity, and most preferably, at least about 90% identity.

In the Claims

For convenience, all pending claims are shown below.

1. [AMENDED] A method of inducing a cytokine in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator comprises [is selected from the group of]

MQPPPLP (SEQ ID NO:1), [LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34),] an active analog thereof, and combinations thereof, [with the proviso that the immunological regulator is not VESYVPLFP (SEQ ID NO:31)] wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.

2. The method of claim 1 wherein the cell is present in a cell culture, a tissue, an organ, or an organism.

3. The method of claim 1 wherein the cell is a mammalian cell.

4. The method of claim 3 wherein the cell is a human cell.

5. [CANCEL] The method of claim 1 wherein the immunological regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2),

DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8),VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

6. [AMENDED] A method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator comprises [is selected from the group of] MQPPPLP (SEQ ID NO:1), [LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34),] an active analog thereof, and combinations thereof, [with the proviso that the immunological regulator is not VESYVPLFP (SEQ ID NO:31)] wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.

7. The method of claim 6 wherein the cell is present in a cell culture, a tissue, an organ, or an organism.

8. The method of claim 6 wherein the cell is a mammalian cell.

9. The method of claim 8 wherein the cell is a human cell.

10. [CANCEL] The method of claim 6 wherein the immunological regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

11. [AMENDED] A method for modulating an immune response in a patient, the method comprising administering to the patient an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator <u>comprises</u> [is selected from the group of] MQPPPLP (SEQ ID NO:1), [LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID

NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34),] an active analog thereof, and combinations thereof, [with the proviso that the immunological regulator is not VESYVPLFP (SEQ ID NO:31)] wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.

12. [CANCEL] The method of claim 11 wherein the immunological regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

13. The method of claim 11 wherein the immunological regulator is administered as part of a dietary supplement.

14. The method of claim 11 wherein the immunological regulator is administered topically.

15. The method of claim 11 wherein the patient is an animal.

16. The method of claim 15 wherein the patient is a human.

17. The method of claim 11 wherein the immune response is a specific immune response.

18. The method of claim 11 wherein the immune response is a nonspecific immune response.

19. The method of claim 11 wherein the immune response is the interferon response or antibody production.

20. [AMENDED] A method for modulating [blood cell] leukocyte proliferation, the method comprising contacting [blood cells] leukocytes with a [blood cell] leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to change the number of [blood cell] leukocyte; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

21. [AMENDED] The method of claim 20 wherein the [blood cells] leukocytes are present in a cell culture or an organism.

22. [AMENDED] The method of claim 20 wherein the [blood cells] leukocytes are mammalian cells.

23. [AMENDED] The method of claim 22 wherein the [blood cells] leukocytes are human cells.

24. [AMENDED] The method of claim 22 wherein the [blood cells] leukocytes are increased in number.

25. [AMENDED] The method of claim 24 wherein the [blood cells] leukocytes are differentiated.

26. [AMENDED] The method of claim 22 wherein the [blood cell] leukocyte regulator is a constituent peptide of colostrinin.

27. [AMENDED] The method of claim 26 wherein the [blood cell] leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP (SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

28. [AMENDED] The method of claim 27 wherein the [blood cell] leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8), YPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

29. [AMENDED] A method for modulating [blood cell] leukocyte proliferation in a patient, the method comprising administering to the patient a [blood cell] leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an analog thereof, and combinations thereof, under conditions effective to change the number of [blood cells] leukocytes; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

30. The method of claim 29 wherein the patient is a human.

31. [AMENDED] The method of claim 29 wherein the [blood cells] leukocytes are increased in number.

32. [AMENDED] The method of claim 31 wherein the [blood cells] leukocytes are differentiated.

33. [AMENDED] The method of claim 29 wherein the [blood cell] leukocyte regulator is a constituent peptide of colostrinin.

34. [AMENDED] The method of claim 33 wherein the [blood cell] leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP (SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

35. [AMENDED] The method of claim 34 wherein the [blood cell] leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8),VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

36. [CANCEL] A cytokine-inducing composition comprising a pharmaceutical carrier and an active agent selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, with the proviso that the active agent is not VESYVPLFP (SEQ ID NO:31).

37. [NEW] A method of inducing a cytokine in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ

ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to a one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.

38. [NEW] A method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP

(SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.

39. [NEW] A method for modulating an immune response in a patient, the method comprising administering to the patient an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.